SPECTRUM PHARMACEUTICALS INC
Form 424B5
July 01, 2009

PROSPECTUS SUPPLEMENT NO. 5 **Filed Pursuant to Rule 424(b)(5)**
(TO PROSPECTUS DATED MAY 5, 2008) **Registration Statement No. 333-150260**

2,936,037 Units
Spectrum Pharmaceuticals, Inc.
Units Consisting of
One Share of Common Stock and
a Warrant to Purchase 0.50 of a Share of Common Stock

We are offering 2,936,037 units, with each unit consisting of one share of our common stock and a warrant to purchase 0.50 of a share of our common stock (and the shares of common stock issuable from time to time upon exercise of the offered warrants), to certain institutional investors pursuant to this prospectus supplement and the accompanying prospectus. The purchase price for each unit is $7.1525. Each warrant has an exercise price of $7.10 per share, and is exercisable for a period of 90 days commencing six months after its issue date. The shares of common stock and the warrants will be issued separately but will be purchased together in this offering.

The warrants will not be listed on any national securities exchange. Our common stock is listed on the NASDAQ Global Market under the symbol SPPI. On June 30, 2009, the last reported sale price of our common stock on the NASDAQ Global Market was $7.65 per share.

This investment involves a high degree of risk. Please see the section entitled Risk Factors beginning on page S-3 of this prospectus supplement.

Rodman & Renshaw, LLC acted as the placement agent on this transaction. The placement agent is not purchasing or selling any of these securities nor is it required to sell any specific number or dollar amount of securities, but has agreed to use its reasonable best efforts to sell the securities offered by this prospectus supplement. We have agreed to pay the placement agent the placement agent fees set forth in the table below.

	Per Unit	Aggregate Offering
Public offering price	$7.1525	$ 21,000,000
Placement agent fees	$ 0.36	$ 1,050,000
Proceeds, before expenses, to us	$6.7945	$ 19,950,000

Delivery of the units will take place no later than July 6, 2009, against payment for such units to be received by us on the same date.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Rodman & Renshaw

The date of this prospectus supplement is June 30, 2009

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Prospectus Supplement

You should rely only on information contained in this prospectus supplement, the accompanying prospectus and the documents we incorporate by reference in this prospectus supplement and the accompanying prospectus. We have not authorized anyone to provide you with information that is different. You should not assume that the information in this prospectus supplement or the accompanying prospectus is accurate as of any date other than the date on the front of this prospectus supplement or the prospectus or that any document that we incorporated by reference in this prospectus supplement or the accompanying prospectus is accurate as of any date other than its filing date. You should not consider this prospectus supplement or the accompanying prospectus to be an offer or solicitation relating to the securities in any jurisdiction in which such an offer or solicitation relating to the securities is not authorized. Furthermore, you should not consider this prospectus supplement or the accompanying prospectus to be an offer or solicitation relating to the securities if the person making the offer or solicitation is not qualified to do so, or if it is unlawful for you to receive such an offer or solicitation.

ABOUT THIS PROSPECTUS SUPPLEMENT

This summary highlights selected information about us, this offering and information appearing elsewhere in this prospectus supplement, in the accompanying prospectus and in the documents we incorporate by reference. This summary is not complete and does not contain all the information you should consider before investing in our securities pursuant to this prospectus supplement and the accompanying prospectus. You should carefully read this entire prospectus supplement and the accompanying prospectus carefully, including the information referred to under the heading Risk Factors in this prospectus supplement and the financial statements and other information that we incorporated by reference in this prospectus supplement and the accompanying prospectus before making an investment decision.

This prospectus supplement supplements the accompanying prospectus filed with our registration statement on Form S-3 (registration file no. 333-150260) as part of a shelf registration process. Under the shelf registration process, we may offer to sell debt securities, preferred stock, common stock, warrants and units, from time to time in one or more offerings up to a total dollar amount of $150,000,000.

This prospectus supplement describes the specific terms of this offering and the accompanying prospectus gives more general information, some of which may not apply to this offering. If the description of the offering varies between this prospectus supplement and the accompanying prospectus, you should rely on the information contained in this prospectus supplement.

Unless the context otherwise requires, references to we , us or the Company in this prospectus supplement and accompanying prospectus shall refer to Spectrum Pharmaceuticals, Inc. Generally, when we refer to this prospectus we are referring to both this prospectus supplement and the accompanying base prospectus combined.

ABOUT SPECTRUM PHARMACEUTICALS

We are a commercial stage biopharmaceutical company committed to developing and commercializing innovative therapies with a focus primarily in the areas of hematology-oncology and urology. We have a fully developed commercial infrastructure that is responsible for the sales and marketing of two drugs in the United States, namely Fusilev and Zevalin®. Our lead developmental drug is apaziquone (formerly EOquin®), which is presently being studied in two large Phase 3 clinical trials for non-muscle invasive bladder cancer.

Spectrum Pharmaceuticals, Inc. is a Delaware corporation that was originally incorporated in Colorado as Americus Funding Corporation in December 1987, became NeoTherapeutics, Inc. in August 1996, was reincorporated in Delaware in June 1997, and was renamed Spectrum Pharmaceuticals, Inc. in December 2002. Our principal executive offices are located at 157 Technology Drive, Irvine, California 92618, and our telephone number at that address is (949) 788-6700. Additional information concerning us can be found in our periodic filings with the Securities and Exchange Commission, or the SEC, which are available on our website at www.spectrumpharm.com and on the SEC s website at www.sec.gov.

THE OFFERING

Common stock offered by us:	2,936,037 shares of common stock.
Common stock to be outstanding after this offering:	41,662,583 shares of common stock.
Warrants offered by us:	Warrants to purchase up to 1,468,020 shares of common stock. Each warrant has an exercise price of $7.10 per share, and is exercisable for a period of 90 days commencing six months after its issue date. This prospectus supplement also relates to the offering of the shares of common stock issuable upon exercise of the warrants.
Use of proceeds:	We intend to use the net proceeds from the sale of the securities under this prospectus supplement for general corporate purposes, including, without limitation, sales and marketing activities, clinical development, making acquisitions of assets, businesses or securities, capital expenditures and for working capital. Please see the section entitled Use of Proceeds.
NASDAQ Global Market Symbol:	SPPI
Risk factors:	This investment involves a high degree of risk. Please see the section entitled Risk Factors beginning on page S-3 of this prospectus supplement.

The number of shares of our common stock that will be outstanding immediately after the offering is based on 38,726,546 shares of our common stock outstanding as of June 30, 2009. Unless we specifically state otherwise, the share information in this prospectus supplement does not include:

- 136,000 shares of common stock issuable upon the conversion of our outstanding Series E convertible preferred stock;
- Approximately 7,000,000 shares of common stock issuable upon the exercise of warrants outstanding prior to this offering;
- 1,468,020 shares of common stock issuable upon the exercise of warrants to be issued to purchasers in this offering;
- Approximately 8,000,000 shares of common stock issuable upon the exercise of stock options outstanding prior to this offering under our equity incentive plans;
- Approximately 10,000,000 shares of common stock available for future grants under our equity incentive plans; and
- Approximately 150,000 shares of common stock available for issuance under our 401(k) profit-sharing plan.

RISK FACTORS

An investment in our securities involves a high degree of risk. Our business, financial condition, operating results and prospects can be impacted by a number of factors, any one of which could cause our actual results to differ materially from recent results or from our anticipated future results. As a result, the trading price of our common stock and the value of the warrants offered hereby could decline, and you could lose part or all of your investment. You should carefully consider the risks described below with all of the other information included in this prospectus supplement, our Annual Report on Form 10-K for the fiscal year ended December 31, 2008, and our other filings with the SEC. Failure to satisfactorily achieve any of our objectives or avoid any of the risks below would likely have a material adverse effect on our business and results of operations.

Risks Related to Our Business

Like other early-stage biotech companies, we have a history of operating losses and our losses may continue to increase as we expand our commercialization and development efforts, and our efforts may never result in profitability.

Our cumulative losses since our inception in 1987 through March 31, 2009 were in excess of $250 million. Our net losses in 2008 and 2007 were approximately $15 million and $34 million, respectively. We expect to continue to incur additional losses as we implement our growth strategy of commercializing our approved drug products and developing our pipeline products for at least the next few years. We may never achieve significant revenues from sales of products or become profitable. Even if we eventually generate significant revenues from sales, we will likely continue to incur losses over the next several years.

Our business does not generate sufficient cash to finance our ongoing operations and therefore, we will likely need to continue to raise additional capital.

Our current commercial operations do not generate sufficient operating cash to finance the clinical development of all our drug products, to commercialize our approved drug products and to capitalize on growth opportunities. While we have been successful recently in generating funds through the licensing and sale of our assets, we have historically relied primarily on raising capital through the sale of our securities and out-licensing our drug products to meet our financial needs. Although we began selling products in 2008, we believe that we may need to continue to raise funds in order to continue drug product commercialization, development and acquisition.

We may not be able to raise additional capital on favorable terms, if at all, particularly with the current volatile financial market conditions. Accordingly, we may be forced to significantly change our business plans and restructure our operations to conserve cash, which would likely involve out-licensing or selling some or all of our intellectual, technological and tangible property not presently contemplated and at terms that we believe would not be favorable to us, and/or reducing the scope and nature of our currently planned drug development and commercialization activities. An inability to raise additional capital would also materially impact our ability to expand operations.

Clinical trials may fail to demonstrate the safety and efficacy of our drug products, which could prevent or significantly delay obtaining regulatory approval.

Prior to receiving approval to commercialize any of our drug products, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the United States Food and Drug Administration, or FDA, and other regulatory authorities in the United States and other countries, that each of the products is both safe and effective. For each drug product, we will need to demonstrate its efficacy and monitor its safety throughout the process. If such development is unsuccessful, our business and reputation would be harmed and our stock price would be adversely affected.

All of our drug products are prone to the risks of failure inherent in drug development. Clinical trials of new drug products sufficient to obtain regulatory marketing approval are expensive and take years to complete. We may not be able to successfully complete clinical testing within the time frame we have planned, or at all. We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent

us from receiving regulatory approval or commercializing our drug products. In addition, the results of pre-clinical studies and early-stage clinical trials of our drug products do not necessarily predict the results of later-stage clinical trials. Later-stage clinical trials may fail to demonstrate that a drug product is safe and effective despite having progressed through initial clinical testing. Even if we believe the data collected from clinical trials of our drug products is promising, such data may not be sufficient to support approval by the FDA or any other United States or foreign regulatory approval. Pre-clinical and clinical data can be interpreted in different ways.

Accordingly, FDA officials could interpret such data in different ways than we or our partners do, which could delay, limit or prevent regulatory approval. The FDA, other regulatory authorities, our institutional review boards, our contract research organizations, or we may suspend or terminate our clinical trials for our drug products. Any failure or significant delay in completing clinical trials for our drug products, or in receiving regulatory approval for the sale of any drugs resulting from our drug products, may severely harm our business and reputation. Even if we receive FDA and other regulatory approvals, our drug products may later exhibit adverse effects that may limit or prevent their widespread use, may cause the FDA to revoke, suspend or limit their approval, or may force us to withdraw products derived from those drug products from the market.

If we are unable to effectively maintain and expand our sales and marketing capabilities, we may be unable to successfully commercialize our approved products.

Historically, we have had limited internal experience in selling, marketing or distributing pharmaceutical products. However, we have recently established a small direct sales force to market our approved products. We also are expanding our direct sales force in connection with the re-launch of Zevalin. If we are not able to effectively hire and train qualified individuals as part of our sales force, our product sales and resulting revenues will be negatively impacted.

If we are unable to expand approved usage of Zevalin, or to maintain or obtain improved reimbursement rates for it, the product s operating results may be harmed, which could adversely affect our financial and operating results.

We intend to seek expansion of the approved uses of Zevalin in the United States. If we are unable to expand the approved uses of Zevalin, or if we are otherwise unable to fulfill our marketing, sales and distribution plans for Zevalin, we may not recognize the full anticipated value of our investment in the product and our financial and operating results could be adversely affected.

In 2007, the Centers for Medicare and Medicaid Services, or CMS, implemented new outpatient reimbursement rates for radiopharmaceuticals, including Zevalin. The new reimbursement rates are significantly below the institution or provider s current acquisition cost for Zevalin. Congress has passed legislation to delay the implementation of those new rates and stabilize reimbursement rates through January 1, 2010, with the intention of giving drug manufacturers and CMS time to reach an agreement that more adequately reflects costs associated with affected pharmaceuticals. However, CMS may not agree to a rate or methodology that provides an acceptable reimbursement on radiopharmaceuticals such as Zevalin. In the event that CMS does not agree to a reimbursement rate that is adequate to cover an institution or provider s acquisition cost for Zevalin, we could face significant difficulty in getting care providers to use Zevalin, which would have an adverse impact on the product s expected operating results, and in turn adversely impact our investment in the product and our financial and operating results.

We may face difficulties in achieving broader market acceptance of Zevalin if we do not invest significantly in our sales and marketing infrastructure.

United States sales of Zevalin have declined over the several years prior to our acquisition of the Zevalin assets. We believe that an enhanced sales and marketing strategy for Zevalin, in conjunction with efforts to obtain approval by the FDA for expanded uses of Zevalin, has significant potential to increase sales of and revenue from Zevalin over the next few years. However, implementation of the sales and marketing strategy for Zevalin, and the efforts to expand approved usage of Zevalin, will require a significant investment of financial and other resources by us for the foreseeable future and may not ultimately increase Zevalin sales or allow us to realize the anticipated benefits from our investment in the product. Additionally, our efforts to establish an effective direct sales force for Zevalin will require significant commitments of both financial and management resources by us, and may not ultimately be successful due a variety of factors, including industry competition for effective sales and marketing personnel or the

inability of us to dedicate the necessary resources to those efforts.

The intellectual property and assets owned by our subsidiary, RIT, are subject to a security agreement with Biogen that secures the entity s payment and other obligations to Biogen, and we have guaranteed all of those obligations.

In connection with the formation of RIT Oncology, LLC, or RIT, RIT entered into a security agreement with Biogen Idec, Inc., or Biogen, pursuant to which RIT granted to Biogen a first priority security interest in all of its assets, which consist of the Zevalin-related intellectual property and other assets RIT. The security agreement secures certain payment, indemnification and other obligations of RIT to Biogen related to Zevalin. If RIT were to default on certain of its obligations to Biogen, or in certain other circumstances generally related to a bankruptcy or insolvency of RIT, Biogen could seek to foreclose on the collateral under the security agreement to obtain satisfaction of RIT s obligations to it. If RIT were to default on its obligations to Biogen, and Biogen were to foreclose on the collateral under the security agreement, RIT s business could be materially and adversely impacted, which could in turn materially and adversely impact our investment in RIT and our financial condition and results of operations.

Furthermore, in connection with the formation of RIT we guaranteed all of RIT s obligations to Biogen. If RIT were to default on its obligations to Biogen, Biogen could require us alone to satisfy all of those obligations under our guarantee.

The financial and other obligations that we would incur could have a material and adverse effect on our financial condition and results of operations.

If we are unable to expand the approved usage of Fusilev, the product s operating results may be harmed, which could adversely affect our financial and operating results.

We have filed a supplemental new drug application for Fusilev for use in combination with 5-FU-containing regimens in the treatment of colorectal cancer. The greatest potential use of this product is in this indication. If we are not able to obtain approval for this indication, we may not recognize the full anticipated value of our investment in the product and our financial and operating results could be adversely affected.

Our drug product Fusilev may not be more cost efficient than competing drugs and otherwise may not have any competitive advantage, which could hinder our ability to successfully commercialize it.

Fusilev is a novel folate analog formulation and the pharmacologically active isomer (the levo-isomer) of the racemic compound calcium leucovorin, a product already approved for the same indications our product is approved for. Leucovorin has been sold as a generic product on the market for a number of years. There are generic companies currently selling the product and therefore, Fusilev competes against a low-cost alternative. Also, Fusilev will be offered as part of a treatment regimen, and that regimen may change to exclude Fusilev. Accordingly, it may not gain acceptance by the medical field or become commercially successful.

The marketing and sale of Fusilev and Zevalin may be adversely affected by the marketing and sales efforts of third parties who sell these products outside the United States.

We have only licensed the rights to develop, market and sell Fusilev in North America, and have licensed the rights to develop, market and sell Zevalin in the United States. Other companies market and sell the same products in other parts of the world. If, as a result of their actions, negative publicity is associated with the product, our own efforts to successfully market and sell these products, may be adversely impacted.

The development of our drug product, apaziquone, may be adversely affected if the development efforts of Allergan, who retained certain rights to the product, are not successful.

In 2008, we entered into a co-development and license agreement with Allergan, Inc., or Allergan, for the worldwide development and commercialization of our drug product, apaziquone. Allergan has agreed to partially fund development and commercialization expenses for apaziquone. We do not fully control the drug development process under the license agreement. In addition, if we do not achieve certain milestones under the license

agreement and it has been determined that failure to achieve these milestones was a result of our actions or inactions, Allergan is entitled to assume additional control over the development process. As a result, success of this product could depend, in part, upon the efforts of Allergan. Allergan may not be successful in the clinical development of the drug, obtaining approval of the product by regulatory authorities, or the eventual commercialization of apaziquone.

The development of our drug product, ozarelix, may be adversely affected if the development efforts of Aeterna Zentaris, who retained certain rights to the product, are not successful.

Aeterna Zentaris licensed the rights to us to develop and market ozarelix in the United States, Canada, Mexico and India. Aeterna Zentaris, or its partners, may conduct their own clinical trials on ozarelix for regulatory approval in all other parts of the world. We will not have control over such development activities and our ability to attain regulatory approvals for ozarelix may be adversely impacted if its efforts are not successful.

The development of our drug product, satraplatin, depends on the efforts of a third party and, therefore, its eventual success or commercial viability is largely beyond our control.

In 2002, we entered into a co-development and license agreement with GPC Biotech AG, or GPC, for the worldwide development and commercialization of our drug product, satraplatin. GPC has agreed to fully fund development and commercialization expenses for satraplatin. We do not have control over the drug development process and therefore the success of this product depends upon the efforts of GPC and any of its sublicensees. GPC may not be successful in the clinical development of the drug, obtaining approval of the product by regulatory authorities, or the eventual commercialization of satraplatin.

The inability to retain and attract key personnel could significantly hinder our growth strategy and might cause our business to fail.

Our success depends upon the contributions of our key management and scientific personnel, especially Dr. Rajesh C. Shrotriya, our Chairman, President and Chief Executive Officer. Dr. Shrotriya has been President since 2000 and Chief Executive Officer since 2002, and has spearheaded our business strategy since that time. The loss of the services of Dr. Shrotriya or any other key personnel could delay or preclude us from achieving our business objectives.

We also require expertise in sales, marketing, pharmaceutical drug development and other areas in order to achieve our business objectives. Competition for qualified personnel among pharmaceutical companies is intense, and the loss of key personnel, or the delay or inability to attract and retain the additional skilled personnel required for the expansion of our business, could significantly damage our business.

As we evolve from a company primarily involved in development to a company also involved in commercialization, we may encounter difficulties in managing our growth and expanding our operations successfully.

We only recently began commercial sales of our products and have had to increase our personnel accordingly, including establishing a direct sales force. In addition, as we advance our drug products through clinical trials, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with such third parties, as well as additional collaborators and suppliers. Maintaining these relationships and managing our future growth will impose significant added responsibilities on members of our management. We must be able to: manage our development efforts effectively; manage our clinical trials effectively; hire, train and integrate additional management, development, administrative and sales and marketing personnel; improve our managerial, development, operational and finance systems and expand our facilities, all of which may impose a strain on our administrative and operational infrastructure.

If we acquire additional businesses, we may not successfully integrate their operations.

We may acquire additional businesses that complement or augment our existing business. Integrating any newly acquired business could be expensive and time-consuming. We may not be able to integrate any acquired business successfully or operate any acquired business profitably. Our future financial performance will depend, in part, on our ability to manage any future growth effectively and our ability to integrate any acquired businesses. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

Our collaborations with outside scientists may be subject to change, which could limit our access to their expertise.

We work with scientific advisors and collaborators at research institutions. These scientists are not our employees and may have other commitments that would limit their availability to us. If a conflict of interest between their work for us and their work for another entity arises, we may lose their services, which could negatively impact our research and development activities.

We may rely on contract research organizations and other third parties to conduct clinical trials and, in such cases, we are unable to directly control the timing, conduct and expense of our clinical trials.

We may rely, in full or in part, on third parties to conduct our clinical trials. In such situations, we have less control over the conduct of our clinical trials, the timing and completion of the trials, the required reporting of adverse events and the management of data developed through the trial than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may have staffing difficulties, may undergo changes in priorities or may become financially distressed, adversely affecting their willingness or ability to conduct our trials. We may experience unexpected cost increases that are beyond our control. Problems with the timeliness or quality of the work of a contract research organization may lead us to seek to terminate the relationship and use an alternative service provider. However, making this change may be costly and may delay our trials, and contractual restrictions may make such a change difficult or impossible. Additionally, it may be impossible to find a replacement organization that can conduct our trials in an acceptable manner and at an acceptable cost.

We are subject to risks associated with doing business internationally.

Since we conduct clinical trials and manufacture our drug products internationally, our business is subject to certain risks inherent in international business, many of which are beyond our control. These risks include, among other things:

maintaining compliance with foreign legal requirements, including employment law;

unexpected changes in foreign regulatory requirements, including quality standards and other certification requirements;

tariffs, customs, duties and other trade barriers;

changing economic conditions in countries where our products are manufactured;

exchange rate risks;

product liability, intellectual property and other claims;

political instability;

new export license requirements; and

difficulties in coordinating and managing foreign operations.

Any of these factors could have an adverse effect on our business, financial condition and results of operations. We may not be able to successfully manage these risks or avoid their effects.

We may have conflicts with our partners that could delay or prevent the development or commercialization of our drug products.

We may have conflicts with our partners, such as conflicts concerning the interpretation of preclinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. If any conflicts arise with any of our partners, such partner may act in a manner that is adverse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our drug product, and in turn prevent us from generating revenues:

- unwillingness on the part of a partner to pay us milestone payments or royalties that we believe are due to us under a collaboration;
- uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations;
- unwillingness by the partner to cooperate in the development or manufacture of the product, including providing us with product data or materials;
- unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities;
- initiation of litigation or alternative dispute resolution options by either party to resolve the dispute;
- attempts by either party to terminate the collaboration;
- our ability to maintain or defend our intellectual property rights may be compromised by our partner s acts or omissions;
- a partner may utilize our intellectual property rights in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or expose us to potential liability;
- a partner may change the focus of their development and commercialization efforts. As previously noted, pharmaceutical and biotechnology companies historically have re-evaluated their priorities following mergers and consolidations, which have been common in recent years in these industries. The ability of our products to reach their potential could be limited if future partners decrease or fail to increase spending relating to such products;
- unwillingness of a partner to fully fund or commit sufficient resources to the testing, marketing, distribution or development of our products; and/or
- unwillingness or ability of a partner to fulfill their obligations to us. A partner may develop alternative products either on their own or in collaboration with others, or encounter conflicts of interest or changes in business strategy or other business issues.

Given these risks, it is possible that any collaborative arrangements which we have or may enter into may not be successful.

Our efforts to acquire or in-license and develop additional drug products may fail, which might limit our ability to grow our business.

Our long-term strategy includes the acquisition or in-license of additional drug products. We are actively seeking to acquire, or in-license, additional commercial drug products as well as drug products that have demonstrated positive pre-clinical and/or clinical data. We have certain criteria that we are looking for in any drug product acquisition and we may not be successful in locating and acquiring, or in-licensing, additional desirable drug products on acceptable terms. In addition, many other large and small companies within the pharmaceutical and biotechnology industry seek to establish collaborative arrangements for product research and development, or otherwise acquire products in late-stage clinical development, in competition with us. We face additional competition from public and private research organizations, academic institutions and governmental agencies in establishing collaborative arrangements for drug products in late-stage clinical development. Many of the companies and institutions that compete against us have substantially greater capital resources, research and development staffs and facilities than we have, and greater experience in conducting business development activities. These entities represent significant competition to us as we seek to expand our portfolio through the in-license or acquisition of compounds. Moreover, while it is not feasible to predict the actual cost of acquiring additional drug products, that cost could be substantial and we may need to raise additional financing, which may further dilute existing stockholders, in order to acquire new drug products.

From time to time we may need to license patents, intellectual property and proprietary technologies from third parties, which may be difficult or expensive to obtain.

We may need to obtain licenses to patents and other proprietary rights held by third parties to successfully develop, manufacture and market our drug products. As an example, it may be necessary to use a third party s proprietary technology to reformulate one of our drug products in order to improve upon the capabilities of the drug product. If we are unable to timely obtain these licenses on reasonable terms, our ability to commercially exploit our drug products may be inhibited or prevented.

We are a small company relative to our principal competitors, and our limited financial resources may limit our ability to develop and market our drug products.

Many companies, both public and private, including well-known pharmaceutical companies and smaller niche-focused companies, are developing products to treat many, if not all, of the diseases we are pursuing or are currently distributing drug products that directly compete with the drugs that we sell or that we intend to develop, market and distribute. Many of these companies have substantially greater financial, research and development, manufacturing, marketing and sales experience and resources than us. As a result, our competitors may be more successful than us in developing their products, obtaining regulatory approvals and marketing their products to consumers.

Competition for branded or proprietary drugs is less driven by price and is more focused on innovation in the treatment of disease, advanced drug delivery and specific clinical benefits over competitive drug therapies. We may not be successful in any or all of our current clinical studies; or if successful, and if one or more of our drug products is approved by the FDA, we may encounter direct competition from other companies who may be developing products for similar or the same indications as our drug products. Companies that have products on the market or in research and development that target the same indications as our products target include Neurocrine Biosciences, Abraxis Bioscience, Inc., Astra Zeneca LP, Amgen, Inc., Bayer AG, Bioniche Life Sciences Inc., Eli Lilly and Co., Novartis Pharmaceuticals Corporation, Genentech, Inc., Bristol-Myers Squibb Company, GlaxoSmithKline, Biogen-IDEC Pharmaceuticals, Inc., OSI Pharmaceuticals, Inc., Cephalon, Inc., Sanofi-aventis, Inc., Pfizer, Inc., AVI Biopharma, Inc., Genzyme Corporation, Shire Pharmaceuticals, Abbott Laboratories, Poniard Pharmaceuticals, Inc., Roche Pharmaceuticals, Johnson & Johnson and others who may be more advanced in the development of competing drug products or are more established. Many of our competitors are large and well-capitalized companies focusing on a wide range of diseases and drug indications, and have substantially greater financial, research and development, marketing, human and other resources than we do. Furthermore, large pharmaceutical companies have significantly more experience than we do in pre-clinical testing, human clinical trials and regulatory approval procedures, among other things.

Our supply of drug products will be dependent upon the production capabilities of contract manufacturing organizations, or CMOs, and component and packaging supply sources, and, if such CMOs are not able to meet our demands, we may be limited in our ability to meet demand for our products, ensure regulatory compliance or maximize profit on the sale of our products.

We have no internal manufacturing capacity for our drug products, and, therefore, we have entered into agreements with CMOs to supply us with active pharmaceutical ingredients and our finished dose drug products. Consequently, we will be dependent on our CMO partners for our supply of drug products. Some of these manufacturing facilities are located outside the United States. The manufacture of finished drug products, including the acquisition of compounds used in the manufacture of the finished drug product, may require considerable lead times. We will have little or no control over the production process. Accordingly, while we do not currently anticipate shortages of supply, there could arise circumstances in which we will not have adequate supplies to timely meet our requirements or market demand for a particular drug product could outstrip the ability of our supply source to timely manufacture and deliver the product, thereby causing us to lose sales. In addition, our ability to make a profit on the sale of our drug products depends on our ability to obtain price arrangements that ensure a supply of product at favorable prices.

Reliance on CMOs entails risks to which we would not be subject if we manufactured products ourselves, including reliance on the third party for regulatory compliance and adherence to the FDA s current Good Manufacturing Practice, or cGMP, requirements, the possible breach of the manufacturing agreement by the CMO and the possibility of termination or non-renewal of the agreement by the CMO, based on its own business priorities, at a time that is costly or inconvenient for us. Before we can obtain marketing approval for our drug products, our CMO facilities must pass an FDA pre-approval inspection. In order to obtain approval, all of the facility s manufacturing methods, equipment and processes must comply with cGMP requirements. The cGMP requirements govern all areas of record keeping, production processes and controls, personnel and quality control. In addition, our CMOs will be subject to on-going periodic inspection by the FDA and corresponding state and foreign agencies for compliance with cGMP regulations, similar foreign regulations and other regulatory standards. We do not have control over our CMOs compliance with these regulations and standards. Any failure of our third party manufacturers or us to comply with applicable regulations, including an FDA pre-approval inspection and cGMP requirements, could result in sanctions being imposed on them or us, including warning letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our products, delay, suspension or withdrawal of approvals, license revocation, seizures or recalls of product, operation restrictions and criminal prosecutions, any of which could significantly and adversely affect our business.

We may not be successful in establishing additional active pharmaceutical ingredient or finished dose drug supply relationships, which would limit our ability to develop and market our drug products.

Success in the development and marketing of our drugs depends in part upon our ability to maintain, expand and enhance our existing relationships and establish new sources of supply for active pharmaceutical ingredients, or API, or for the manufacture of our finished dose drug products. We do not presently intend to focus our research and development efforts on developing APIs or manufacturing of finished dosage form for our drugs. In addition, we currently have no capacity to manufacture APIs or finished dose drug products and do not intend to spend our capital resources to develop the capacity to do so. Therefore, we must rely on relationships with API suppliers and other CMOs, to supply our APIs and finished dose drug products. We may not be successful in maintaining, expanding or enhancing our existing relationships or in securing new relationships with API suppliers or CMOs. If we fail to maintain or expand our existing relationships or secure new relationships, our ability to develop and market our drug products could be harmed.

We rely on contract suppliers to supply our existing products, and will likely do the same for other products that we may develop, commercialize or acquire in the future. Contract suppliers may not be able to meet our needs with respect to timing, cost, quantity or quality. All of our suppliers are sole-source suppliers, including for Zevalin and Fusilev, and no currently qualified alternative suppliers exist.

If we are unable to obtain a sufficient supply of our required products and services on acceptable terms, or if we should encounter delays or difficulties in our relationships with our manufacturers, or if any required approvals by the FDA and other regulatory authorities do not occur on a timely basis, we will lose sales. Moreover, contract

suppliers that we may use must continually adhere to current good manufacturing practices enforced by the FDA. If the facilities of these suppliers cannot pass an inspection, we may lose FDA approval of our products. Failure to obtain products for sale for any reason may result in an inability to meet product demand and a loss of potential revenues.

Our drug products may not be more effective, safer or more cost-efficient than a competing drug and otherwise may not have any competitive advantage, which could hinder our ability to successfully commercialize our drug products.

Any drug product for which we obtain FDA approval must compete for market acceptance and market share. Drugs produced by other companies are currently on the market for each disease type we are pursuing. Even if one or more of our drug development products ultimately receives FDA approval, our drug products may not have better efficacy in treating the target indication than a competing drug, may not have a more favorable side-effect profile than a competing drug, may not be more cost-efficient to manufacture or apply, or otherwise may not demonstrate a competitive advantage over competing therapies. Accordingly, even if FDA approval is obtained for one or more of our drug development products, they may not gain acceptance by the medical field or become commercially successful.

The size of the market for our potential products is uncertain.

We often provide estimates of the number of people who suffer from the diseases that our drugs are targeting. However, there is limited information available regarding the actual size of these patient populations. In addition, it is uncertain whether the results from previous or future clinical trials of drug products will be observed in broader patient populations, and the number of patients who may benefit from our drug products may be significantly smaller than the estimated patient populations.

If actual future payments for allowances, discounts, returns, rebates and chargebacks exceed the estimates we made at the time of the sale of our products, our financial position, results of operations and cash flows may be materially and negatively impacted.

We recognize product revenue net of estimated allowances for discounts, returns, rebates and chargebacks. Such estimates require our most subjective and complex judgment due to the need to make estimates about matters that are inherently uncertain. Based on industry practice, pharmaceutical companies, including us, have liberal return policies. Generally, we are obligated to accept from customers the return of pharmaceuticals that have reached their expiration date up to 12 months after their expiration. We authorize returns for damaged products and exchanges for expired products in accordance with our return goods policy and procedures. In addition, like our competitors, we also give credits for chargebacks to wholesale customers that have contracts with us for their sales to hospitals, group purchasing organizations, pharmacies or other retail customers. A chargeback is the difference between the price the wholesale customer (in our case, the GPOs) pays (wholesale acquisition cost) and the price that the GPO s end-customer pays for a product (contracted customer). Since we have only recently begun commercial distribution of our products, we do not have historical data on returns and allowances. Although we have estimated the allowances very conservatively, actual results may differ significantly from our estimated allowances for discounts, returns, rebates and chargebacks. Changes in estimates and assumptions based upon actual results may have a material impact on our results of operations and/or financial condition. Such changes to estimates will be made to the financial statements in the year in which the estimate is charged. In addition, our financial position, results of operations and cash flows may be materially and negatively impacted if actual future payments for allowances, discounts, returns, rebates and chargebacks exceed the estimates we made at the time of the sale of our products.

Risks Related to Our Industry

If third-party payors do not adequately reimburse providers for any of our products, if approved for marketing, we may not be successful in selling them.

Our ability to commercialize any products successfully will depend in part on the extent to which reimbursement will be available from governmental and other third-party payors, both in the United States and in foreign markets. Even if we succeed in bringing one or more products to the market, the amount reimbursed for our products may be insufficient to allow us to compete effectively and could adversely affect our profitability.

Reimbursement by a governmental and other third-party payors may depend upon a number of factors, including a governmental or other third-party payor s determination that use of a product is:

a covered benefit under its health plan;

safe, effective and medically necessary;

appropriate for the specific patient;

cost-effective; and

neither experimental nor investigational.

Obtaining reimbursement approval for a product from each third-party and governmental payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to each payor. We may not be able to provide data sufficient to obtain reimbursement.

Eligibility for coverage does not imply that any drug product will be reimbursed in all cases or at a rate that allows us to make a profit. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not become permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on payments allowed for lower-cost drugs that are already reimbursed, may be incorporated into existing payments for other products or services, and may reflect budgetary constraints and/or Medicare or Medicaid data used to calculate these rates. Net prices for products also may be reduced by mandatory discounts or rebates required by government health care programs or by any future relaxation of laws that restrict imports of certain medical products from countries where they may be sold at lower prices than in the United States.

The consolidation of drug wholesalers and other wholesaler actions could increase competitive and pricing pressures on pharmaceutical manufacturers, including us.

We sell our pharmaceutical products primarily through wholesalers. These wholesale customers comprise a significant part of the distribution network for pharmaceutical products in the United States. This distribution network is continuing to undergo significant consolidation. As a result, a smaller number of large wholesale distributors control a significant share of the market. We expect that consolidation of drug wholesalers will increase competitive and pricing pressures on pharmaceutical manufacturers, including us. In addition, wholesalers may apply pricing pressure through fee-for-service arrangements, and their purchases may exceed customer demand, resulting in reduced wholesaler purchases in later quarters. We cannot assure you that we can manage these pressures or that wholesaler purchases will not decrease as a result of this potential excess buying.

Rapid bio-technological advancement may render our drug products obsolete before we are able to recover expenses incurred in connection with their development. As a result, our drug products may never become profitable.

The pharmaceutical industry is characterized by rapidly evolving biotechnology. Biotechnologies under development by other pharmaceutical companies could result in treatments for diseases and disorders for which we are developing our own treatments. Several other companies are engaged in research and development of compounds that are similar to our research. A competitor could develop a new biotechnology, product or therapy that has better efficacy, a more favorable side-effect profile or is more cost-effective than one or more of our drug products and thereby cause our drug products to become commercially obsolete. Some of our drug products may become obsolete before we recover the expenses incurred in their development. As a result, such products may never become profitable.

Competition for patients in conducting clinical trials may prevent or delay product development and strain our limited financial resources.

Many pharmaceutical companies are conducting clinical trials in patients with the disease indications that our drug products target. As a result, we must compete with them for clinical sites, physicians and the limited number of patients who fulfill the stringent requirements for participation in clinical trials. Also, due to the confidential nature of clinical trials, we do not know how many of the eligible patients may be enrolled in competing studies and who are consequently not available to us for our clinical trials. Our clinical trials may be delayed or terminated due to the inability to enroll enough patients to complete our clinical trials. Patient enrollment depends on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites and the eligibility criteria for the study. The delay or inability to meet planned patient enrollment may result in increased costs and delays or termination of the trial, which could have a harmful effect on our ability to develop products.

Failure to obtain regulatory approval outside the United States will prevent us from marketing our product candidates abroad.

We have plans to market certain of our existing and future product candidates in non-U.S. markets in the future. In order to market our existing and future product candidates in the European Union and many other non-U.S. jurisdictions, we must obtain separate regulatory approvals. We have had limited interactions with non-U.S. regulatory authorities, and the approval procedures vary among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more non-U.S. regulatory authorities does not ensure approval by regulatory authorities in other countries or by the FDA. The non-U.S. regulatory approval process may include all of the risks associated with obtaining FDA approval as well as other risks specific to the jurisdictions in which we may seek approval. We may not obtain non-U.S. regulatory approvals on a timely basis, if at all. We may not be able to file for non-U.S. regulatory approvals and may not receive necessary approvals to commercialize our existing and future product candidates in any market.

Even after we receive regulatory approval to market our drug products, the market may not be receptive to our drug products upon their commercial introduction, which would negatively affect our ability to achieve profitability.

Our drug products may not gain market acceptance among physicians, patients, healthcare payors and the medical community. The degree of market acceptance of any approved drug products will depend on a number of factors, including:

the effectiveness of the drug product;

the prevalence and severity of any side effects;

potential advantages or disadvantages over alternative treatments;

relative convenience and ease of administration;

the strength of marketing and distribution support;

the price of the drug product, both in absolute terms and relative to alternative treatments; and

sufficient third-party coverage or reimbursement.

If our drug products receive regulatory approval but do not achieve an adequate level of acceptance by physicians, healthcare payors and patients, we may not generate drug product revenues sufficient to attain profitability.

Guidelines and recommendations published by various organizations can reduce the use of our products.

Government agencies promulgate regulations and guidelines directly applicable to us and to our products. However, professional societies, practice management groups, insurance carriers, physicians, private health/science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to healthcare providers, administrators and payers, and patient communities. Recommendations of government agencies or these other groups/organizations may relate to such matters as usage, dosage, route of administration and use of related therapies and reimbursement of our products by government and private payers. Organizations like these have in the past made recommendations about our products. Recommendations or guidelines that are followed by patients and healthcare providers could result in decreased use and/or dosage of our products.

Any recommendations or guidelines that result in decreased use, dosage or reimbursement of our products could adversely affect our product sales and operating results materially. In addition, the perception by the investment community or stockholders that such recommendations or guidelines will result in decreased use and dosage of our products could adversely affect the market price for our common stock.

Our failure to comply with governmental regulations may delay or prevent approval of our drug products and/or subject us to penalties.

The FDA and comparable agencies in foreign countries impose many requirements on the introduction of new drugs through lengthy and detailed clinical testing and data collection procedures, and other costly and time consuming compliance procedures. While we believe that we are currently in compliance with applicable FDA regulations, if our partners, our contract research organizations, our CMOs or we fail to comply with the regulations applicable to our clinical testing, the FDA may delay, suspend or cancel our clinical trials, or the FDA might not accept the test results. The FDA, an institutional review board at our clinical trial sites, our third party investigators, any comparable regulatory agency in another country, or we, may suspend clinical trials at any time if the trials expose subjects participating in such trials to unacceptable health risks. Further, human clinical testing may not show any current or future drug product to be safe and effective to the satisfaction of the FDA or comparable regulatory agencies, or the data derived from the clinical tests may be unsuitable for submission to the FDA or other regulatory agencies.

Once we submit a drug product for commercial sale approval, the FDA or other regulatory agencies may not issue their approvals on a timely basis, if at all. If we are delayed or fail to obtain these approvals, our business and prospects may be significantly damaged. Even if we obtain regulatory approval for our drug products, we, our partners, our manufacturers, and other contract entities will continue to be subject to extensive requirements by a number of national, foreign, state and local agencies. These regulations will impact many aspects of our operations, including testing, research and development, manufacturing, safety, effectiveness, labeling, storage, quality control, adverse event reporting, record keeping, approval, advertising and promotion of our future products. Failure to comply with applicable regulatory requirements could, among other things, result in:

- warning letters;
- fines;
- changes in advertising;
- revocation or suspension of regulatory approvals of products;
- product recalls or seizures;
- delays, interruption, or suspension of product distribution, marketing and sale;
- civil or criminal sanctions; and
- refusals to approve new products.

The discovery of previously unknown problems with drug products approved to go to market may raise costs or prevent us from marketing such product or change the labeling of our products or take other potentially limiting or costly actions if we or others identify side effects after our products are on the market.

The later discovery of previously unknown problems with our products may result in restrictions of the drug product, including withdrawal from the market. In addition, the FDA may revisit and change its prior determinations with regard to the safety and efficacy of our products. If the FDA s position changes, we may be required to change our labeling or to cease manufacture and marketing of the challenged products. Even prior to any formal regulatory action, we could voluntarily decide to cease the distribution and sale or recall any of our products if concerns about their safety or effectiveness develop.

On September 27, 2007, President George W. Bush signed into law the Food and Drug Administration Amendments Act of 2007, or the FDAAA, significantly adding to the FDA s authority, including allowing the FDA to (i) require sponsors of marketed products to conduct post-approval clinical studies to assess a known serious risk, signals of serious risk or to identify an unexpected serious risk; (ii) mandate labeling changes to products, at any point in a product s lifecycle, based on new safety information and (iii) require sponsors to implement a Risk Evaluation and Mitigation Strategy (REMS) for a product which could include a medication guide, patient package insert, a communication plan to healthcare providers, or other elements as the FDA deems are necessary to assure safe use of the drug (either prior to approval or post-approval as necessary), which could include imposing certain restrictions on distribution or use of a product. Failure to comply with the new requirements, if imposed on a sponsor by the FDA under the FDAAA, could result in significant civil monetary penalties or other administrative actions by FDA. Further, regulatory agencies could change existing, or promulgate new, regulations at any time which may affect our ability to obtain or maintain approval of our existing or future products or require significant additional costs to obtain or maintain such approvals.

Our failure to comply with FDA (and related) regulations applicable to our business may subject us to sanctions, which could damage our reputation and adversely affect our business condition.

In the U.S., the FDA, and comparable state regulatory agencies and enforcement authorities, impose requirements on us as a manufacturer and marketer of prescription drug products. Drug manufacturers are required to register with the FDA, and are required to comply with various regulatory requirements regarding drug research, manufacturing, distribution, reporting and recordkeeping. Most drug products must be approved by the FDA prior to marketing, and companies are required to comply with numerous post-marketing requirements. Companies are also subject to periodic inspection by the FDA for compliance with cGMP and other applicable regulations.

Further, drug manufacturers are required to comply with FDA requirements for labeling and advertising, as well as other Federal and state requirements for advertising. This includes a prohibition on promotion for unapproved or off-label uses, e.g., promotion of products for uses that are not described in the product s FDA-approved labeling. While a physician may prescribe a medication for off-label uses where appropriate, companies may not generally promote drug products for off-label uses.

If the FDA or other Federal and state agencies believe that a company is not in compliance with applicable regulations, they have various enforcement authorities to address violations. The FDA can issue a warning letter and seek voluntary compliance from a company in the form of remedial or corrective action. The FDA may also impose civil money penalties by administrative action, and through judicial enforcement seek actions including injunctions, seizures, and criminal penalties. The FDA or other Federal and state authorities may also seek operating restrictions on a company in order to achieve compliance, including termination or suspension of company activities. Such agencies and enforcement authorities may also disseminate information to the public about their enforcement actions.

If we were to become subject to any FDA or similar enforcement action related to any of our drug products, our business condition could be adversely affected, and the public release of such information could be damaging to our reputation.

Legislative or regulatory reform of the healthcare system and pharmaceutical industry related to pricing or reimbursement may hurt our ability to sell our products profitably or at all.

In both the United States and certain foreign jurisdictions, there have been and may continue to be a number of legislative and regulatory proposals to change the healthcare system and pharmaceutical industry in ways that could impact our ability to sell our products profitably. Sales of our products depend in part on the availability of reimbursement from third-party payors such as government health administration authorities, private health insurers, health maintenance organizations including pharmacy benefit managers and other health care-related organizations. Both the Federal and state governments in the U.S. and foreign governments continue to propose and pass new legislation and regulations designed to contain or reduce the cost of health care. Such legislation and regulations may result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce the prices charged for prescription drugs. This could harm our ability to market our products and generate revenues.

It is possible that proposals will be adopted, or existing regulations that affect the coverage or pricing of pharmaceutical and other medical products may change, before any of our products are approved for marketing. Cost control initiatives could decrease the price that we receive for any of our products that we are developing. In addition, third-party payors are increasingly challenging the price and cost-effectiveness of medical products and services. Significant uncertainty exists as to the reimbursement status of newly-approved pharmaceutical products.

In some foreign countries, particularly in the European Union, prescription drug pricing is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our profitability will be negatively affected.

If we market products in a manner that violates health care anti-kickback or other fraud and abuse laws, we may be subject to civil or criminal penalties, including exclusions from participation in Federal health care programs.

The Federal health care program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid or other federally financed health care programs. This statute applies to arrangements between pharmaceutical manufacturers and prescribers, purchasers and formulary managers. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the Federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as providing free product to customers with the expectation that the customers would bill Federal programs for the product; reporting to pricing services inflated average wholesale prices that were then used by Federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicaid for non-covered off-label uses; and submitting inflated best price information to the Medicaid Rebate Program.

The Health Insurance Portability and Accountability Act of 1996 also created prohibitions against health care fraud and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services.

The majority of states also have statutes or regulations similar to these Federal laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. In addition, some states have laws that require pharmaceutical companies to adopt comprehensive compliance programs. For example, under California law, pharmaceutical companies must comply with both the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and the PhRMA Code on Interactions with Healthcare Professionals, as amended. We have adopted and implemented a compliance program which we believe satisfies the applicable requirements of California law.

Sanctions under these Federal and state laws may include civil monetary penalties, exclusion of a manufacturer s products from reimbursement under government programs, criminal fines and imprisonment. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our past, present or future operations are found to be in violation of any of the laws described above or other similar governmental regulations to which we are subject, we may be subject to the applicable penalty associated with the violation which could adversely affect our ability to operate our business and our financial results.

If we are unable to adequately protect our technology or enforce our patent rights, our business could suffer.

Our success with the drug products that we develop will depend, in part, on our ability and the ability of our licensors to obtain and maintain patent protection for these products. We currently have a number of United States and foreign patents issued and pending, however, we primarily rely on patent rights licensed from others. Our license agreements generally give us the right and/or obligation to maintain and enforce the subject patents. We may not receive patents for any of our pending patent applications or any patent applications we may file in the future. If our pending and future patent applications are not allowed or, if allowed and issued into patents, if such patents and the patents we have licensed are not upheld in a court of law, our ability to competitively exploit our drug products would be substantially harmed. Also, such patents may or may not provide competitive advantages for their respective products or they may be challenged or circumvented by our competitors, in which case our ability to commercially exploit these products may be diminished.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in pharmaceutical and biotechnology patents has emerged to date in the United States. The laws of many countries may not protect intellectual property rights to the same extent as United States laws, and those countries may lack adequate rules and procedures for defending our intellectual property rights. Filing, prosecuting and defending patents on all our products or product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions and may not be covered by any of our patent claims or other intellectual property rights.

Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. We do not know whether any of our patent applications will result in the issuance of any patents, and we cannot predict the breadth of claims that may be allowed in our patent applications or in the patent applications we license from others.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we or our licensors might not have been the first to make the inventions covered by each of our or our licensors pending patent applications and issued patents, and we may have to participate in expensive and protracted interference proceedings to determine priority of invention;
- we or our licensors might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative product candidates or duplicate any of our or our licensors product candidates;
- our or our licensors pending patent applications may not result in issued patents;

our or our licensors issued patents may not provide a basis for commercially viable products or may not provide us with any competitive advantages or may be challenged by third parties;

others may design around our or our licensors patent claims to produce competitive products that fall outside the scope of our or our licensors patents;

we may not develop or in-license additional patentable proprietary technologies related to our product candidates; or

the patents of others may prevent us from marketing one or more of our product candidates for one or more indications that may be valuable to our business strategy.

Moreover, an issued patent does not guarantee us the right to practice the patented technology or commercialize the patented product. Third parties may have blocking patents that could be used to prevent us from commercializing our patented products and practicing our patented technology. Our issued patents and those that may be issued in the future may be challenged, invalidated or circumvented, which could limit our ability to prevent competitors from marketing related product candidates or could limit the length of the term of patent protection of our product candidates. In addition, our competitors may independently develop similar technologies. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

We also rely on trade secret protection and contractual protections for our unpatented, confidential and proprietary technology. Trade secrets are difficult to protect. While we enter into confidentiality agreements with our employees, consultants and others, these agreements may not successfully protect our trade secrets or other confidential and proprietary information. It is possible that these agreements will be breached, or that they will not be enforceable in every instance, and that we will not have adequate remedies for any such breach. Likewise, although we conduct periodic trade secret audits of certain partners, vendors and contract manufacturers, these trade secret audits may not protect our trade secrets or other confidential and proprietary information. It is possible that despite having certain trade secret audited security measures in place, trade secrets or other confidential and proprietary information may still be leaked or disclosed to a third party. It is also possible that our trade secrets will become known or independently developed by our competitors.

If we are unable to adequately protect our technology, trade secrets or proprietary know-how, or enforce our patents, our business, financial condition and prospects could suffer.

Intellectual property rights are complex and uncertain and therefore may subject us to infringement claims.

The patent positions related to our drug products are inherently uncertain and involve complex legal and factual issues. Although we are not aware of any infringement by any of our drug products on the rights of any third party, there may be third party patents or other intellectual property rights relevant to our drug products of which we are not aware. Third parties may assert patent or other intellectual property infringement claims against us with products. This could draw us into costly litigation as well as result in the loss of our use of the intellectual property that is critical to our business strategy.

Intellectual property litigation is increasingly common and increasingly expensive and may result in restrictions on our business and substantial costs, even if we prevail.

Patent and other intellectual property litigation is becoming more common in the pharmaceutical industry. Litigation is sometimes necessary to defend against or assert claims of infringement, to enforce our patent rights, including those we have licensed from others, to protect trade secrets or to determine the scope and validity of proprietary rights of third parties. Currently, no third party is asserting that we are infringing upon their patent rights or other intellectual property, nor are we aware or believe that we are infringing upon any third party s patent rights or other intellectual property. We may, however, be infringing upon a third party s patent rights or other intellectual property, and litigation asserting such claims might be initiated in which we would not prevail, or we would not be

able to obtain the necessary licenses on reasonable terms, if at all. All such litigation, whether meritorious or not, as well as litigation initiated by us against third parties, is time-consuming and very expensive to defend or prosecute and to resolve. In addition, if we infringe the intellectual property rights of others, we could lose our right to develop, manufacture or sell our products or could be required to pay monetary damages or royalties to license proprietary rights from third parties. An adverse determination in a judicial or administrative proceeding or a failure to obtain necessary licenses could prevent us from manufacturing or selling our products, which could harm our business, financial condition and prospects.

If our competitors prepare and file patent applications in the United States or Europe that claim technology we also claim, we may have to participate in interference proceedings required by the United States Patent and Trademark Office to determine priority of invention or opposition proceedings in Europe, both of which could result in substantial costs, even if we ultimately prevail. Results of interference and opposition proceedings are highly unpredictable and may result in us having to try to obtain licenses in order to continue to develop or market certain of our drug products.

We may be subject to damages resulting from claims that we, or our employees, have wrongfully used or disclosed alleged trade secrets of our employees former employers.

Many of our employees were previously employed at universities or biotechnology or pharmaceutical companies, including our competitors or potential competitors. Althoug